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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,528	06/23/2000	Jan Eirik Ellingsen	06275-199001	9997

26161 7590 02/22/2005

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EXAMINER

CULBERT, ROBERTS P

ART UNIT	PAPER NUMBER
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1763

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/602,528

Applicant(s)

ELLINGSEN ET AL.

Examiner

Roberts Culbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,27,34,44 and 82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,27,34,44 and 82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 1/6/05 have been fully considered but they are not persuasive.

Applicant has argued that since Chung et al. teach "the fluoride treated samples after acid soaking retained the integrity of the coating and showed similar surface morphology of the coating as the original (fluoride-treated) sample without acid soaking. On the other hand, those samples without fluoride treatment showed considerable surface damage and morphology change of the coating after acid soaking." Clearly, the fluoride-treated samples of Chung exhibit a different morphology than the samples without fluoride treatment.

Applicant is incorrect. The acetic acid treatment step referred to by Chung et al. is an entirely separate and distinct step from the fluoride treatment step. See Col. 3, Lines 40-44 of Chung et al. It is the acid soaking and not the fluoride treatment that causes changes in the morphology. There is no suggestion that fluoride treatment causes morphological changes, in fact, it is clear from the cited text of Chung et al. that the fluoride treatment prevents morphological changes associated with the acid soaking.

Applicant has argued that since the implant of Chung already contains calcium, there is no reason for one skilled in the art to apply calcium.

The argument is not persuasive because the purpose of the calcium ion solution treatment is not merely to provide the implant with calcium. The prior art process is used to test the biocompatibility of the implant. As stated by Applicant "calcium deposition may be obtained through naturally occurring biological processes once the implant is inserted into the bone tissue. Since calcium is present in the body, calcium will be deposited on the surface of an implant once it is implanted into the body." Since calcium is necessarily deposited to an implant when it is inserted in the body, regardless of whether the implant previously contained calcium, there is a motivation to perform the prior art compatibility test.

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***Allowable Subject Matter***

The indicated allowability of claims 27 and 34 is withdrawn in view of the newly discovered reference to Suzuki et al. Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 23 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "essentially" in the phrase "essentially the same morphology" in claims 23 and 82 is a relative term that renders the claim indefinite. The term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,039,546 to Chung et al.**

Chung teaches a process of treating a metallic bone implant consisting essentially of treating the metallic bone implant with an aqueous solution containing fluoride ions in a concentration greater than 0% and up to 3% (Col. 3, Lines 27-29) where the aqueous solution is free from sodium and sodium ions, and being a solution of a fluoride selected from the group consisting of lithium fluoride, cesium fluoride,

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potassium fluoride, ammonium fluoride, stannous fluoride, or any combination thereof. (Col. 2, Lines 56-63)

Since the treatment process of Chung is the same as the claimed invention, either the morphological changes would be the same as claimed by applicant, or arise from essential features not present in the claims. Chung further indicates that the surface of the metallic bone implant after the treatment with the aqueous solution containing fluoride ions has essentially the same morphology as the surface of the implant before said treatment, otherwise a comparison of acid treated samples could not be made as stated (Col. 4, Lines 14-26)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP-3146679 to Haruyuki.**

Haruyuki teaches a method for treating the surface of a titanium biorepair implant and increasing the strength of the bond between bone tissue and the metallic implant. Haruyuki describes treatment of

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the titanium implant in a 1-6% solution of hydrofluoric acid. It is assumed that the hydrofluoric acid solution is free of sodium ions.

Although Haruyuki stresses the use of a post treatment with hydrogen peroxide, the use of hydrofluoric acid alone is clearly contemplated in Comparative Example 2. The results described in Table No.1 indicate that post treatment is not needed to affect the surface properties. Note the values of Rz are the same for example 2 and comparative example 2. The purpose of the hydrogen peroxide post treatment is to reduce tissue irritation (Page 4 Line 30). Haruyuki teaches that only slight changes in morphology are needed to increase the attachment strength of the implant. Haruyuki indicates that features with an average depth below 0.5  $\mu\text{m}$  would have a small anchoring effect (Page 4 Lines 21-26).

Although it is not explicitly stated in Haruyuki, it may be assumed that the surface of the metallic bone implant after the treatment with the aqueous solution containing fluoride ions has essentially the same morphology as the surface of the implant before said treatment since the claimed treatment processes are the same and Haruyuki indicates that the changes in average feature size are small compared to the untreated implant. Note that the untreated implant has average feature depth of 0.3 $\mu\text{m}$ , and treated implants may have an average feature size of 0.5  $\mu\text{m}$ .

**Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,039,546 to Chung et al. in view of the admitted prior art.**

As applied above, Chung teaches the method of the invention substantially as claimed, but does not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment of an implant with a solution of calcium ions in order to determine the biocompatibility of the treated implant.

It would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

**Claims 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,039,546 to Chung et al. in view of U.S. Patent 4,746,532 to Suzuki et al.**

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As applied above, Chung teaches the method of the invention substantially as claimed, but does not teach that the metallic bone implant has a surface layer constituted by a metallic oxide such as titanium dioxide.

Suzuki et al. teaches that it is conventional in the art to oxidize a titanium implant surface to form a titanium oxide layer prior to applying a ceramic material such as hydroxyapatite. (Col. 3, Lines 1-66)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the hydroxyapatite coating of Chung in the conventional manner taught by Suzuki et al. in order to provide excellent adhesion without the use of a bonding agent as taught by Suzuki et al. (Col. 2, Lines 21-25)

#### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberts Culbert whose telephone number is (571) 272-1433. The examiner can normally be reached on Monday-Friday (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Mills can be reached on (571) 272-1439. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. Culbert

*R. Culbert*

*P. Hassanzedeh  
Primary Examiner  
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